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EDITOR'S NOTES

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CHARACTERISTICS OF DEPARTMENT OF DEFENSE MEDICAL MALPRACTICE CLAIMS: AN UPDATE BY RICHARD L. GRANVILLE, M.D., J.D., ET AL

Since 1986, the rate of claims per 100 physicians in DoD has been in the range of 4.6–8. Nearly one-fourth of patients involved in DoD malpractice claims are less than two years of age. Approximately two-thirds of claims involve patients over the age of 19. Fifty-four percent of patients filing DoD medical malpractice claims were dependents of active duty service members, and approximately 30 percent were retirees or their dependents. With regard to the severity of injury for patients involved in DoD claims, nearly 23 percent died, 16 percent experienced no injury, and the remainder had some degree of injury.

Of 2,910 claims, approximately one-quarter were settled administratively, over one-third were denied, and 25 percent proceeded to litigation. Fourteen percent of these were settled without a trial. Only 10 percent of claims were formally litigated in a federal court. The government successfully defended approximately 60 percent of those cases. Forty percent of 3,977 claims involved allegations related to diagnoses, 21 percent related to surgery, 14 percent related to treatment, 13 percent related to obstetrics, 5 percent related to medication, 2.2 percent included inappropriate or unprofessional behavior of a clinician, breach of confidentiality or privacy, and failure to follow an institutional policy or procedure, 2 percent related to intravenous procedures and blood products, 1.4 percent related to anesthesiology, 0.5 percent related to patient monitoring, and 0.5 percent related to biomedical equipment/products.

Of 2,777 claims, 83.2 percent attributed fault to physicians, nonphysicians were involved in 8.5 percent, facility and equipment problems were involved in 4.3 percent, and system or management failures occurred in 2.7 and 1.3 percent, respectively. Within a treatment facility, the locale for the alleged malpractice was an inpatient setting for 64.8 percent of the claims and an outpatient setting for 28.4 percent. The remainder of allegations were distributed among dental and ancillary services. The most frequent inpatient services were obstetrics/gynecology, surgery, and medicine. The most frequent outpatient services were emergency care, medicine, and primary medical care. The primary provider was a physician in 90 percent of the claims, physician assistants in 2.2 percent, dentists in 2.0 percent, and registered nurses in 1.3 percent. Of 1,343 claims, obstetrics/gynecology (22.5) and surgery (18.5) are the most frequently represented specialties. Of 2,983 claims, the standard of care was considered met in 65.4 percent of claims and not met in 28.0 percent of claims. No determination was rendered in the remainder because of inadequate information available to reviewers. Of 3,026 claims, diagnoses of pregnancy, childbirth, and the puerperium were the most frequently represented diagnostic group (17.2 percent of claims). Approximately 14 percent involved neoplasms, and 10.2 percent involved the circulatory system. The most frequent specific diagnoses are cancer of the breast, ischemic heart disease, fetal/placental problems, cancer of the lung, female genital pain, acute appendicitis and ectopic pregnancy. The most frequently specified surgical procedures are cesarean section, vaginal delivery, abdominal laparotomy, breast, coronary artery bypass, Fallopian tube, and spinal cord surgeries. A total of \$309,158,644 was paid for 1,281 claims through 1995. Payments were made in approximately 40 percent of reported claims.

The database represents a constant effort to analyze malpractice information critically and employ it properly within the entire spectrum of risk management activities. The diagnoses, procedures, specialties, and medical services that appear frequently may well be candidates for worthwhile focused studies.

MANAGED CARE LIABILITY BY FRANK T. FLANNERY, M.D., J.D., COL, MC, USA

"Managed care" encompasses various mechanisms by which large systems administer the financing and delivery of health care. It is revamping many aspects of the traditional physician-patient relationship. The current momentum is toward a system in which decisions are subject to insurer review, with a goal of cost containment. There are changes in physician liability which have accompanied the managed care revolution. Some of these changes have already spawned litigation, and some have the potential to alter the legal landscape. With the emphasis on reducing specialty referrals and limiting sophisticated diagnostic studies, primary care providers' gatekeeping role has increased their liability for failure to diagnose. Claims arising from care rendered in physicians' offices have seen a sharp increase. This increase in office-based claims is coupled with the trend away from hospitalization and aggressive specialty evaluations and could represent a shifting of liability risks to the office-based generalist.

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Insurer authorization of hospital stays has provoked much discussion in one leading case, Wickline v. State of California. Lois Wickline experienced problems associated with her back and legs. Her postoperative course was characterized by pain, spasm of lower extremity vessels, and hallucinations. Five days following initial surgery, Ms. Wickline was returned to the operating room where a lumbar sympathectomy was performed to stop vasospasms and prevent clotting. Her stormy postoperative course convinced the surgeon that a 10-day hospital extension was medically necessary. The surgeon disagreed with Medi-Cal's decision, but thought Medi-Cal had the power to limit the duration of hospitalization. Accordingly, he discharged the patient four days earlier than planned. Nine days after discharge, she was readmitted with a secondary infection of her right groin incision, a mottled right foot and a cool right leg. A regimen of anticoagulants, antibiotics, whirlpool baths, and bed rest was unsuccessful, and the patient's right leg was amputated. The patient sued Medi-Cal arguing that Medi-Cal's refusal to grant a full 8-day extension represented negligent premature discharge which caused the loss of the limb. The court of appeals reversed the judgment for the plaintiff. Thus, the state of California and Medi-Cal ultimately escaped liability. Even though Ms. Wickline's physicians were not named as defendants in this case, the court stated that physicians must act in the patient's best interests, regardless of cost containment regulations.

The growth of managed care will continue to present both medical and legal challenges, and case law will better define the legal responsibilities of all managed care participants. For now, primary legal and professional responsibilities remain with the patient, not the managed care organization.

BREAST CANCER MALPRACTICE CLAIMS BY PAUL J. CONNORS, M.D., J.D., CAPT, MC, USNR

In 1995, medical malpractice cases involving the diagnosis and treatment of breast cancer have become the most common form of liability claim filed against physicians in the United States.

The Armed Forces Institute of Pathology (AFIP) experience with breast cancer related malpractice claims from 1980 to 1990 included 80 claims related to the delayed diagnosis of breast cancer. Reviewers considered 56 (70 percent) of the cases meritorious and substantiable malpractice claims. The most frequently encountered problems included failure to perform a

biopsy (38 cases), especially when mammography was considered negative (19 cases), misreading of positive findings on mammography (5 cases), misreading of histopathology specimens (3 cases), inadequate biopsies (3 cases), and communication failures (3 cases). There were 68 closed cases, 75 percent with payment. Indemnification ranged from \$6,000 to \$1,000,000, with a median payment of \$100,000 and a mean of \$162,050.

Kern, in 1991, published a survey of all negligence trials involving the diagnosis of breast cancer from 1971 through 1990. The survey revealed 45 cases litigated in 38 states during those 20 years. Fifty-eight percent were less than 39 years old, the mean age was 40 years, and all were less than 59 years old. The patient presented with a painless mass in 65 percent of cases. Pain, skin changes, and breast discharges exemplified symptoms reported in more than 20 percent of cases. The diagnostic evaluation was limited to a physical examination in 51 percent of patients. Among the 20 mammograms obtained, 80 percent were considered normal. The average delay in diagnosis was 15 months. In 32 cases, where the stage of disease at diagnosis was available, there were two cases at stage I, 22 at stage II, and the remainder at stage III or IV. In 12 cases, metastatic disease or death occurred by the time of litigation. The cases involving death included two patients who had initially presented when pregnant. The cases with the largest payments involved young patients, pregnant patients, and patients experiencing the longest delays.

Practitioners would be wise to take heed of certain tenets derived from liability cases:

- Breast cancer can occur in relatively young patients, those in their 20's and 30's, some when pregnant.
- The clinical presentation of breast cancer includes patients with painful or tender breast lesions.
- Diagnostic mammography does not currently exist, and clinicians should consider those terms mutually exclusive.
- Breast cancer can be diagnosed now only upon the satisfaction of histopathologic criteria.
- The potential for false negative biopsies is heightened when evaluating small breast lesions, and special procedures, such as tissue specimen radiographs and early repeat mammograms, may be indicated.
- Careful counseling and assiduous reevaluation may be necessary to clarify the diagnosis of breast cancer, a disease where patient denial should be anticipated.

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MEDICAL PRACTICE GUIDELINES: IS COOKBOOK MEDICINE HERE? BY WILLIAM J. OETGEN, COL, MC, USAR, AND MARY JO WILEY, R.N., J.D.

What are practice guidelines? How are they developed? What are the legal implications of practice guidelines? How will they affect medical practice now and in the future? These are questions posed by physicians with increasing frequency. Practice guidelines are defined as "systematically developed statements of recommendation for patient management to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."

A driving impetus to publish practice guidelines occurred in the mid 1980's and resulted from the rising cost of health care, an increasing awareness of medical outcomes research, and the issue of inappropriate care. With potential reimbursement and public determination of appropriate clinical care at stake, many medical specialty organizations quickly realized an interest in publishing clinical practice guidelines. Congress formalized the process on the federal level in 1989 when it established the Agency for Health Care Policy and Research (AHCPR). The AHCPR is part of the United States Public Health Service and functions at the same administrative level as the Center for Disease Control and the National Institutes of Health. The first guideline was published in March 1992 and dealt with postoperative pain management. Reaction by providers and the public appeared quite favorable, as with the next two federal guidelines devoted to urinary incontinence and decubitus ulcers. The following two guidelines, regarding the evaluation and treatment of cataracts and mental depression, however, stimulated some controversy.

State legislatures have also passed laws dealing with practice guidelines and their implementation. Minnesota and Washington have enacted health care reform legislation that created commissions to develop and promulgate practice guidelines to minimize unnecessary and ineffective care. Florida's statute specifically addresses the issue of cost effectiveness as well as the quality of care. Maryland's new health care reform package establishes a multidisciplinary commission, including three physicians, to research and develop practice guidelines.

Empirical evidence that clinicians are applying practice guidelines to patient care is sparse. The *AMA News* reported that an American College of Physicians survey, scheduled for publication in January

1996, has found a generally favorable reaction by physicians to guidelines. Their theoretical ability to improve quality of care, reduce inappropriate care, minimize differences in geographic usage, and limit malpractice exposure has captured the imaginations of candidates, legislators, policy makers and quality reviewers. Clinicians expected to apply them have been cautiously slower with their embrace.

NECK PAIN BY STEPHEN V. MAWN, M.D., J.D., CDR., MC, USN

A 62-year-old man, with a history of diabetes mellitus and degenerative spine disease, presented with a ten day history of fever, sharp lower neck pain, bilateral shoulder discomfort, and URI symptoms with productive brown sputum. His white blood count was 14,500 and a chest x-ray was unremarkable. The physician diagnosed acute bronchitis and prescribed antibiotics. Two weeks later, the patient was evaluated for persistent neck, upper back and bilateral shoulder pain. The physician diagnosed acute and chronic cervical pain with diabetic peripheral neuropathy. Cervical spine x-rays and CT were performed. There is no indication that the attending physician reviewed the x-rays or received a contemporaneous report. Several days later, the patient presented to the emergency department with severe lower neck and shoulder pain. He was afebrile. A hilar mass was suspected on chest xray, and the patient was referred to the primary care clinic. A chest x-ray was performed. A reviewing physician ruled out a hilar mass, diagnosed "probable DJD, R/O herniated disc", scheduled an MRI of the cervical spine, and requested neurosurgical consultation on a routine basis. Cervical spine CT was performed. The radiologist's written report noted "a mottled appearance to the C6 vertebral body"and that "osteolytic lesions can not be excluded." There is no indication that the physician reviewed the study or the written report. The patient underwent surgery 26 days after initial clinical presentation. Epidural and prevertebral abscesses were drained, and a C6/7 discectomy with an anterior interbody fusion was performed. Cultured surgical specimens grew Escherichia coli. Perioperatively, the patient reported mild weakness confined to wrist extensors and hand intrinsics bilaterally. The patient submitted a malpractice claim for negligent delay in diagnosing his spinal abscess, resulting in permanent neurologic injury. Specialty reviewers concluded that the care rendered was substandard, and the claim was settled administratively.

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Infection that directly invades the epidural space, urinary tract infections, peridontal abscesses, pharyngitis, pneumonia, and mastoiditis can result in a spinal epidural abscess. Typically, spinal abscesses are located posteriorly in the thoracic or lumbar spine. Staphylococcus aureus is the organism most often involved, although Mycobacterium tuberculosis has been reported in one-fourth of same series. Although anterior abscesses are uncommon, the majority of them occur with cervical osteomyelitis. Typically, neck pain does not indicate a serious medical condition. Similar to other severely ill patients who present with common complaints, the timely identification of patients with neck pain who harbor serious disease can be crucial to successful treatment and optimal clinical outcome.

EXPERT TESTIMONY IN MEDICAL MALPRACTICE LITIGATION BY JENNIFER A. DOWD, J.D.

Expert opinions are critical to the resolution of legal disputes when professional negligence is alleged. Problems can arise when no expert testimony is offered, or when the proffered expert lacks expertise in the defendant's specific area of professional practice. There can also be difficulties when the basic theory supporting an expert's testimony has neither demonstrated sufficient reliability nor gained broad acceptance within the scientific community.

Experts testify to assist a judge or jury. Their testimony must be relevant to the issues being tried and should reference information outside the realm of common knowledge. The Federal Rules of Evidence state that adequate "knowledge, skill, experience, training or education" is necessary for an expert to qualify, while individual states can require clinical experience, or have a locality requirement. It is imperative to know the criteria for the jurisdiction where the suit is litigated.

In one notable case, the Supreme Court of Missis-sippi expressly replaced the precedent "locality rule" in 1985 with a national standard for professional care. A common standard was found to apply to all physicians practicing in the same specialty throughout the United States, and the court pointed out that patients should expect similar postoperative care regardless of whether they were "in Cleveland, Ohio, or Pascagoula, Mississippi." The now common practice of holding local physicians to a national standard enlarged the pool of potential expert witnesses. Applying a national standard allows any competent and

qualified physician in that specialty to offer an opinion as to the adequacy of care rendered by a local physician.

For almost 70 years, many courts applied the Frye rule to include or exclude scientific evidence. This rule was derived from a criminal case heard in federal court in the District of Columbia. The court reviewed whether a primitive lie detector test using systolic blood pressure should have been admitted. The court found no "general acceptance" within the scientific community regarding the theory, and the expert was consequently rejected. The court emphasized that "general acceptance" within the appropriate professional community would be the criterion courts would look to in deciding admissibility. Many commentators criticized the Frye rule. In an attempt to resolve this controversy, the U.S. Supreme Court decided Daubert v. Merrell Dow Pharmaceuticals, Inc. At trial, the defendant pharmaceutical firm objected to the substantive use of expert testimony to establish a link between birth defects and Bendectin. Employing language similar to Frye, the trial court excluded the evidence. The Supreme Court remanded it for a new trial after explicitly rejecting the applicability of "general acceptance" to scientific evidence in the federal courts. The opinion does not address the value, worth, or reliability of the evidence offered. The opinion declared an end to the era of the Frye rule as an absolute determinant of admissibility. If the testimony will assist the trier of fact in understanding a relevant piece of evidence, then such testimony will be permitted from qualified experts.

Different courts examining the admissability of similar facts can reach different conclusions. Statutes of the controlling jurisdiction, court precedents and evidentiary rules can be determinative. The *Daubert* and *Frye* tests are both worth knowing, since *Daubert* directly controls only federal courts and a significant number of states still utilize the older test of "general acceptance" for admissibility.

To obtain the full text including references, literature and case law review, and valuable clinical practice tips worth 5 CME credits, follow the instructions under the Editor's Notes on page 1.

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